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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,504	02/22/2002	Olaf Reinhold	030903.0004.UTL	8672

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EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	10/080,504	REINHOLD ET AL.	
	Examiner	Art Unit	
	AARON J. LEWIS	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/07/2004 (RCE)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-19,21-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Voges ('841).

As to claim 1, Voges discloses a device (fig.2) for delivering an aerosolized compound (e.g. nicotine at col.5, line 58), the device comprising: a reservoir (10) that stores the compound; a system comprising an entry port (12) and an element (14) to generate particles of a desired size for physical ejection through one or more apertures (15) from an ejection head (14) of the element, wherein said particles comprise a compound (e.g. nicotine at col.5, line 58), and wherein said system is fluidly connected (11) to a reservoir (10); and a housing (2,3) comprising an inlet (7) and an outlet (5) between which is formed an airflow path (see bold arrows in fig.2 extending from outside of housing 2,3 through inlet 7 and through outlet 5) and in which at least the ejection head is disposed in the air flow path (i.e. as illustrated in fig.2) downstream of the inlet (7) and upstream from the outlet (5), wherein the housing provides for a substantially unobstructed airflow between the ejection head and the outlet when air traverses the airflow path from the inlet to the outlet.

As to claims 2 and 3, in Voges the compound (col.5, line 58) is a pharmaceutical compound and is stored in the reservoir (10) in a liquid formulation (col.5, line 58 discloses nicotine dissolved in water).

As to claims 4-7, Voges (col.9, line 53-col.10, line 21) discloses a variety of suitable drugs for delivery by the device. These drugs include proteins and hormones (e.g. corticosteroids and antidiuretic hormone), and small molecules (e.g. budesonide) as well as other drugs which are fully capable of being gene delivery vehicles.

As to claim 8, the reservoir (10) and particle generating system (14,15) in Voges (fig.2) are illustrated as being located within housing (2,3).

As to claim 9, the housing of Voges (fig.2) is aerodynamically shaped (e.g. cylindrically shaped thereby providing for easy flow of air therethrough and around).

As to claim 10, the reservoir (10) of Voges is disclosed as being detachable (col.6, lines 37-40).

As to claim 11, the reservoir (10) and particle generating system (11,12,14,15) of Voges is illustrated (e.g. in fig.2) as being integrated into a single unit.

As to claim 12, the particle generating system of Voges is an electronic ejection device (col.6, lines 45-51).

As to claim 13, Voges discloses the electronic ejection device uses heat (20 and col.6, lines 26-30) to generate particles ejected from the ejection head.

As to claim 14, Voges discloses the electronic ejection device includes a piezoelectric component (col.10, lines 52-54) to generate particles ejected from the ejection head.

As to claims 15-17, Voges discloses the desire particle size is one which allows particles to transit to and be deposited in alveoli (col.9, lines 37-47). That is, Voges recognizes that particles having a diameter less than 5 microns are preferred because particles of this size range will follow respiratory passages. One of ordinary skill would recognize respiratory passages to include alveoli.

As to claim 18, fig.2 of Voges illustrates substantially unobstructed airflow being substantially laminar prior to exiting the housing outlet (5).

As to claim 19, fig.2 of Voges illustrates substantially unobstructed airflow comprises a substantially homogeneous mixture of ejected compound and air from inlet (7) prior to exiting the housing outlet (5).

Claims 21-24 are substantially equivalent in scope to claims 1 and 18 and are anticipated by Voges for the reasons set forth above with respect to claims 1 and 18.

Claims 25-42 are substantially equivalent in scope to claims 1-19 and are anticipated by Voges for the reasons set forth above with respect to claims 1-19. Voges as discussed above also discloses a digitally controlled electronic ejection (col.6, lines 45-51) of aerosolized medicament.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Voges ('841) in view of Gonzalez ('614).

The difference between Voges and claim 20 is an inner surface of the housing is proximal to the ejection head and extending to the outlet is contoured to minimize turbulence.

Gonzalez, in a device for delivering an aerosolized compound (page 1, col.2, lines 100+), teaches an inner surface of the housing is proximal to the aerosol generation system and extending to the outlet is contoured (A' to a2 to e2 of fig.1). The contouring of the inner surface of the housing of Gonzalez would implicitly cause variations in the flow rate and flow pattern of the aerosol being formed as it passes therethrough (e.g. smaller diameter portions would cause increased flow rate and more laminar flow whereas increased diameter portions would cause decreased flow rate and relatively more turbulent flow.

It would have been obvious to modify the inner surface of the housing proximal to the ejection head to make it contoured because it would have provided a means for controlling the flow rate and flow pattern of the aerosol being formed as taught by Gonzalez.

Drawings

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "...inner surface of the housing is proximal to the ejection head and extending to the outlet is contoured to

minimize turbulence." as recited in claim 20 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

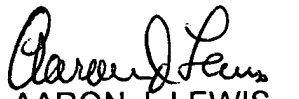
Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant devices for aerosolizing medicament.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
March 12, 2005